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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/643,192

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Michael John Robert White

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EXAMINER

SCHLIENTZ, NATHAN W

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

10/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/643,192	Applicant(s) WHITE ET AL.	
	Examiner Nathan W. Schlientz	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 33-39 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 33-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38 and 39 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/18/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Invention III, claims 38-39, in the reply filed on 16 August 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

Claims 1 and 33-39 are pending. Claims 1 and 33-37 are withdrawn from further consideration as being drawn to a non-elected invention. Claims 38-39 are examined herein on the merits for patentability. No claim is allowed at this time.

Information Disclosure Statement

The information disclosure statement (IDS) filed 18 August 2003 has been fully considered. However, the document listed under "Other References" is cited in error. The date of the cited document should read 1996, as opposed to 1966. Appropriate correction is respectfully requested.

Claim Objections

1. Claim 39 is objected to because of the following informalities: the second line contains the misspelling "saliucylaldehyde". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, claim 38 recites, "wherein said indole and 4-terpinenol are synergistic cofactor substances for said salicylaldehyde."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1616

1. Claims 38-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10 and 12 of U.S. Patent No. 6,495,512 in view of U.S. Patent No. 4,122,085.

The instant claims are drawn to a process for eliminating at least one microorganism selected from the group consisting of *Eschericia coli*, *Enterococcus hirae*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Saccharomyces cerevisae* from the scalp epidermis or hair by applying indole, terpinenol-4, and salicylaldehyde. The '512 patent is drawn to a process for eliminating at least one microorganism selected from the group consisting of *Eschericia coli*, *Enterococcus hirae*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Saccharomyces cerevisae* from a solid or semi-solid surface or a three-space by applying salicylaldehyde and at least one organoleptically-compatible antimicrobial synergism cofactor selected from a group which includes indole and terpinenol-4. The '512 patent further teaches the salicylaldehyde and cofactor in a 1:1 ratio (column 21, lines 5-10).

The '512 patent does not claim the solid or semi-solid surface or three-space to comprise the scalp epidermis or scalp hair, as in the instant claims. However, the '085 patent teaches that *Staphylococcus aureus* is a bacteria that normally resides in the hair (column 16, lines 16-20).

Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art at the time of the instant invention to use the process claimed in the '512 patent in order to eliminate at least one microorganism selected from the group consisting of *Eschericia coli*, *Enterococcus hirae*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*,

Art Unit: 1616

and *Saccharomyces cerevisiae* from the scalp epidermis or hair because the '085 patent reasonably teaches that *Staphylococcus aureus* is a bacteria that normally resides in the hair.

2. Claims 38-39 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10 and 12 of copending Application No. 10/291,124 in view of U.S. Patent No. 4,122,085.

The instant claims are drawn to a process for eliminating at least one microorganism selected from the group consisting of *Eschericia coli*, *Enterococcus hirae*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Saccharomyces cerevisiae* from the scalp epidermis or hair by applying indole, terpinenol-4, and salicylaldehyde. The '124 patent application is drawn to a process for eliminating at least one microorganism selected from the group consisting of *Eschericia coli*, *Enterococcus hirae*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Saccharomyces cerevisiae* from a solid or semi-solid surface or a three-space by applying salicylaldehyde and at least one organoleptically-compatible antimicrobial synergism cofactor selected from a group which includes indole and terpinenol-4. The '124 patent application further teaches the salicylaldehyde and cofactor in a 1:1 ratio (paragraph [0234]).

The '124 patent application does not claim the solid or semi-solid surface or three-space to comprise the scalp epidermis or scalp hair, as in the instant claims.

Art Unit: 1616

However, the '085 patent teaches that *Staphylococcus aureus* is a bacteria that normally resides in the hair (column 16, lines 16-20).

Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art at the time of the instant invention to use the process claimed in the '124 patent application in order to eliminate at least one microorganism selected from the group consisting of *Eschericia coli*, *Enterococcus hirae*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Saccharomyces cerevisae* from the scalp epidermis or hair because the '085 patent reasonably teaches that *Staphylococcus aureus* is a bacteria that normally resides in the hair.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1616

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,417,184 (hereinafter Wakeman et al.), Isshiki et al., J. Japanese Soc. Food Sci. Tech., 1996, 43(5): 535-540 (hereinafter Isshiki et al.), U.S. Patent No. 5,453,276 (hereinafter Nakatsu et al.), Himejima et al., J. Agric. Food Chem., 1992, 40: 245-248 (hereinafter Himejima et al.), and Leach et al., Flavour and Fragrance Journal, 1999, 14(5): 322-332 (hereinafter Leach et al.).

Applicant claims:

Applicants claim a process for eliminating *Escherichia coli*, *Enterococcus hirae*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* or *Saccharomyces cerevisiae* from the scalp epidermis or scalp hair and imparting fragrance thereto, comprising applying a hair spray formulation comprising a mixture of indole, 4-terpinenol, and salicylaldehyde in a 1:1:1 ratio.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Wakeman et al. teach that salicylaldehyde is microbially active against *Staphylococcus aureus* (column 5, lines 40-56 and 74), and can be formulated in a composition for external biocidal use, such as in shampoos and the like (column 1, lines 15-18).

Isshiki et al. teach that salicylaldehyde showed antimicrobial effects against *Saccharomyces cerevisiae*, *Staphylococcus aureus* and *Escherichia coli* (Abstract;

Art Unit: 1616

page 535, 2nd column, last paragraph; page 536, 1st column, first paragraph; and Table 2).

Nakatsu et al. teach that indole enhances the antimicrobial activities of certain naturally occurring substances, whose combination shows greater antimicrobial activity, particularly against *Pseudomonas aeruginosa* (column 1, lines 10-14 and 64-67; and column 2, line 1). Nakatsu et al. further teach indole in shampoo formulations.

Himejima et al. teach that indole is an antimicrobial agent active against *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, and *Saccharomyces cerevisiae* (page 246, Table I; page 247, 1st paragraph, last paragraph through page 247, 2nd column, last full paragraph). Himejima et al. further teach that indole is capable of enhancing the antimicrobial activity of other compounds (page 247, 1st column, first full paragraph). Himejima et al. also teach these compounds as suitable cosmetics for use on skin, hair, and oral problems (page 245, 1st column, 3rd paragraph under INTRODUCTION).

Leach et al. teach that terpinen-4-ol is active against *Pseudomonas aeruginosa*, *Escherichia coli*, and *Staphylococcus aureus* (page 327, 23rd compound under p-Methane; and page 331, 1st column, lines 49-51 without counting spaces).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Neither Wakeman et al., Isshiki et al., Nakatsu et al., Himejima et al. nor Leach et al. teach a composition comprising a combination of salicylaldehyde, indole and terpinen-4-ol. However, Wakeman et al. and Nakatsu et al. teach salicylaldehyde and

Art Unit: 1616

indole, respectively, for use in shampoo compositions for antimicrobial activity against *Pseudomonas aeruginosa* and *Staphylococcus aureus*. Also, Leach et al. teach that terpinen-4-ol is effective against *Pseudomonas aeruginosa*, *Escherichia coli*, and *Staphylococcus aureus*; Isshiki et al. teach salicylaldehyde as an antimicrobial against *Saccharomyces cerevisiae*, *Staphylococcus aureus* and *Escherichia coli*; and Himejima et al. teach that indole is an antimicrobial agent active against *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, and *Saccharomyces cerevisiae*.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to combine salicylaldehyde, indole, and terpinen-4-ol in a shampoo formulation in a process for eliminating *Pseudomonas aeruginosa*, *Escherichia coli*, and *Staphylococcus aureus*.

Such would have been obvious in the absence of evidence to the contrary because it is generally *prima facie* obvious to use in combination two or more ingredients that have previously been used separately for the same purpose to form a third composition useful for that same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. *In re Kerkhoven* 626 F.2d 646, 850, 205 USPQ 1069, 1072 (CCPA 1980).

It is noted by the examiner that neither Wakeman et al., Isshiki et al., Nakatsu et al., Himejima et al. nor Leach et al. teach a 1:1:1 ratio of salicylaldehyde, indole, and 4-terpinenol. However, the examiner respectfully points out the following from MPEP

Art Unit: 1616

2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to discover the optimum or workable ranges of salicylaldehyde, indole, and 4-terpinenol by routine experimentation.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Also, it is noted that instant claims 38-39 are directed to a composition comprising salicylaldehyde, indole and 4-terpinenol, wherein said indole and 4-terpinenol are synergistic cofactor substances for said salicylaldehyde. It is also noted that the instant specification provides synergistic data for the combination of salicylaldehyde

Art Unit: 1616

with indole, and salicylaldehyde with 4-terpinenol (Table I), as well as an example comprising a combination of salicylaldehyde, indole, and terpinenol-4 (Example II). However, the instant specification does not provide data for synergistic antimicrobial efficacy for the combination of salicylaldehyde, indole and 4-terpinenol.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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